

### Remarks

Claims 12-16 and 30-58 are pending in this application. Claims 12-16 and 30-58 are properly supported by the specification as filed. No new matter has been introduced.

#### The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

On pages 2-3 of the Office Action, claims 12-16 and 30-41 are rejected as allegedly obvious over U.S. Patent No. 5,120,758 to Satoh ("Satoh") in view of U.S. Patent No. 6,124,320 to Woosley et al. ("Woosley"). In particular, it is alleged that Satoh discloses compounds useful as selective lipoxygenase inhibitors, and teaches that these compounds can be combined with other agents such as lipoxygenase receptor antagonists and antihistamines. It is further alleged that because Woosley discloses methods for treating allergic rhinitis using norastemizole while avoiding adverse effects associated with the administration of astemizole, and that norastemizole can be combined with other therapeutic agents, it would have been obvious for one of ordinary skill in the art to combine the disclosure of Satoh and Woosley and reach the subject matter recited by the pending claims. Applicant respectfully traverses this rejection.

This application is a division of U.S. Application No. 09/721,668, filed November 27, 2000, which is a continuation of U.S. Application No. 09/059,572, filed April 14, 1998. Woosley was filed on December 16, 1996, and issued on September 26, 2000. Therefore, Woosley is a § 102(e) reference.<sup>1</sup> However, this application and Woosley were commonly owned by Sepracor Inc. at the time this application was filed. Thus, the claims pending in this application cannot be rejected as obvious over Woosley. *See* 35 U.S.C. § 103(c). For this reason alone, Applicant respectfully submits that the rejection of claims 12-16 and 30-41 under 35 U.S.C. § 103 should be withdrawn. However, even if Woosley could form a basis for rejecting the claims under 35 U.S.C. § 103, the claims are not obvious over the combination of Satoh and Woosley for at least the following reasons.

As the Examiner is well-aware, the Patent Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995); *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). To

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<sup>1</sup> Applicant notes that Woosley is a continuation of U.S. Application No. 08/182,685, which is a continuation-in-part of U.S. Application No. 07/940,054 ("the '054 application"). An international application corresponding to the '054 application was published as WO\_94/07495 on April 14, 1994.

establish a *prima facie* case of obviousness, the Patent Office must first show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, it must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure.

Hindsight cannot be used to reject a claim as obvious. *In re Sernaker*, 702 F.2d 989, 994 (Fed. Cir. 1983). Third, the Patent Office must show that the prior art teaches or suggests all the claim limitations. Manual of Patent Examining Procedure § 2143; *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). These criteria must be satisfied with factual and objective evidence found in the prior art: an examiner's conclusory statements cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

Satoh discloses a genus of compounds that can reportedly be used as 5-lipoxygenase inhibitors. Satoh, Abstract. Satoh alleges that these compounds can be used in combination with another therapeutic agent "selected from e.g. an anti-inflammatory agent with cyclooxygenase inhibiting activity, a leukotriene receptor antagonist, a thromboxane synthetase inhibitor, a thromboxane receptor antagonist, an antihistamine, a platelet activating factor (PAF) antagonist or a serotonin receptor antagonist." *Id.* col. 13, lines 13-24. Clearly, Satoh does not place any limits as to what "another therapeutic agent" may be. More important, Satoh does not provide any motivation to single out from all of the possible therapeutic agents it does disclose the particular class of antihistaminic agents.

Even if Satoh did provide some suggestion to select an antihistaminic agent as "another therapeutic agent," it still would not suggest a combination comprising the particular compound norastemizole. This is because Satoh provides yet another, non-exhaustive list of possible antihistaminic agents, which contains "astemizole, loratadine, terfenadine, chlorpheniramine and the like." *Id.* col. 13, lines 36-37 (emphasis added). There is no teaching or suggestion whatsoever in Satoh as to whether any specific antihistaminic agent would be particularly desirable when used in combination with the 5-lipoxygenase inhibitors to which it is directed. In short, it is only with the aid of hindsight, using Applicant's invention as a roadmap, can one possibly single out from the incredible number of potential "another therapeutic agent" disclosed by Satoh—the particular antihistamine astemizole. See *In re Sernaker*, 702 F.2d at 994.

The Examiner apparently believes that one would have been motivated to combine Satoh and Woosley because Satoh discloses astemizole as one example of an antihistaminic agent, and because Woosley discloses that norastemizole can be used for the same indications that astemizole is used for, while avoiding adverse effects associated with the administration of astemizole. Applicant respectfully disagrees.

The prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination. *See C.R. Bard Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998), citing *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985). In this case, it is clear that choosing astemizole from among the broad range of therapeutic agents disclosed in Satoh, and combining that selection with a reference that discloses the use of norastemizole is simply not possible without the use of impermissible hindsight. Consequently, Applicant respectfully requests that the rejection of claims 12-16 and 30-41 under 35 U.S.C. § 103 be withdrawn.

### Conclusion

Applicant respectfully submits that all claims currently pending in this application are allowable, and requests that their rejections be withdrawn.

No fee is believed due for this submission. Should any additional fees be required for this submission or to avoid abandonment of the application, please charge such fees to Deposit Account No. 16-1150.

Respectfully submitted,

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 45,479  
Max Bachrach (Reg. No.)  
**Jones Day**  
51 Louisiana Avenue, N.W.  
Washington, DC 20001-2113  
(202) 879-3939

For: Anthony M. Insogna (Reg. No. 35,203)  
**Jones Day**  
12750 High Bluff Drive Suite 300  
San Diego, CA 92130  
(858) 314-1200